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| EXAMINER | |
|---|---|
| HOWARD, ZACHARY C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/990,046 | DE SAUVAGE ET AL. | |
| | Examiner | Art Unit | |
| | Zachary C. Howard | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-54* is/are rejected.

7)☒ Claim(s) *29,30,39,40 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Sequence Alignment #1

## DETAILED ACTION

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Zachary C. Howard, Art Unit 1646, Technology 1600.

### *Status of Application, Amendments and/or Claims*

The amendment of 4/15/05 has been entered in full. The specification and figures are amended. Claims 29, 39 and 49 are amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 29-54 are under consideration in the instant application.

### *Priority*

The 4/15/05 amendment to the first line of the specification is sufficient to establish priority to the previously filed application.

### *Specification*

The 4/15/05 amendment to the specification has been entered in full.

However, the disclosure is still objected to because of the following informality:

Figures 2A and 2B show the amino acid sequence of human *Ptch* in Figures 2A and 2B but do not refer to the sequence by sequence identifier (SEQ ID NO: X) in either the drawing or the Brief Description of the Drawings. M.P.E.P. 2422.02 states: "It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO: X") must be used, either in the drawing or in the Brief Description of the Drawings" (emphasis added).

Appropriate correction is required.

### *Withdrawn Objections and/or Rejections*

The following page numbers refer to the previous Office Action (12/20/04).

The rejection of claims 29-34, 37, 39-44, 47, 49-50, and 53 under 35 U.S.C. § 101 at pg 3 for being directed to non-statutory subject matter is withdrawn in view of the amended claims (4/27/05).

The rejection of claims 29-35, 37-45, 47-51, and 53-54 under 35 U.S.C. § 102(e) at pg 3, and claims 36,46, and 52 under U.S.C. § 103(a) at pg 4-5 is withdrawn in view of Applicant's submission of the outcome of Interference 105,081.

Please see new claim objections and rejections, below.

### *Claim Objections*

Claims 29, 30, 39, 40 and 49 are objected to because of the following informalities:

(1) Claims 29, 39 and 49 contain the following extraneous characters following the period at the end of the claim: "[page 49, lines 33-36]" These characters should be removed from the claims.

(2) Claims 29, 30, 39 and 40 and contain the term "Figure 1 (SEQ ID NO: 2)". For clarity, this should be amended to read "SEQ ID NO: 2".

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112, 1st paragraph, scope of enablement*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 31-39 and 41-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified antibody that binds to a *patched-2* polypeptide of SEQ ID NO: 2 does not reasonably provide enablement for an antibody that binds a variant of a polypeptide of SEQ ID NO: 2.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to a genus of antibodies which bind to a *patched-2* polypeptide with two characteristics: 1) at least 91%, 92%, 93% or 95% sequence identity to SEQ ID NO: 2 and 2) the ability to bind to a hedgehog polypeptide or a *Smoothened* polypeptide.

The specification provides a single working example of a patched-2 polypeptide with greater than 91% identity to SEQ ID NO: 2 and with the ability to bind to a hedgehog or *Smoothened* polypeptide. This patched-2 polypeptide is the polypeptide of SEQ ID NO: 2. The specification does not teach any other examples of a member of the genus. While the specification asserts that other members of the genus exist, the specification does not provide any specific guidance besides the single working example regarding identification of those members of each genus that will bind a hedgehog or *Smoothened* polypeptide. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The specification does not provide sufficient guidance as to how to make patched-2 polypeptides that are not 100% identical to SEQ ID NO: 2, but which still retain the property of binding a hedgehog or *Smoothened* polypeptide.

While the specification provides an activity that can be used to evaluate the claimed variants or compounds for usefulness (ability to bind a hedgehog or *Smoothened* polypeptide), the specification does not provide example of said variants or compounds that retain such activity, nor sufficient guidance so as to enable one of skill in the art to make such a variant. The specification has failed to teach which amino acids could be modified so as to produce a polypeptide that is not identical and yet still retain the activity of the polypeptide. Applicant has not given any guidance as to which

amino acid substitutions, deletions or insertions to make to achieve any desired property. Applicant has not defined a difference in structure, or difference in function, between the protein corresponding to said patched-2 protein and variants of said protein. If a variant of the protein corresponding to said hedgehog protein is to have a structure and function similar to the protein corresponding to said patched-2 then the specification has failed to teach one of skill in the art which amino acid substitutions, deletions or insertions to make that will preserve the structure and function of the protein corresponding to said hedgehog. Conversely, if a patched-2 protein variant need not have a disclosed property; the specification has failed to teach how to use such a variant.

With regard to variants of a patched-2 protein, or functional fragments of a hedgehog protein, the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. Particular regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions [see Wells (18 September 1990) "Additivity of Mutational Effects in Proteins." Biochemistry **29**(37): 8509-8517; Ngo *et al.* (2 March 1995) "The Protein Folding Problem and Tertiary Structure Prediction, Chapter 14: Computational Complexity Protein Structure Prediction, and the Levinthal Paradox" pp. 492-495]. However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions.

Although the specification outlines art-recognized procedures for producing variants (see pg 11), this is not adequate guidance as to the nature of active variants that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, it may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone [Bork (2000) "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle." Genome Research **10**:398-400; Skolnick and Fetrow (2000) "From gene to protein structure and function: novel applications of computational approaches in the genomic era." Trends in Biotech. **18**(1): 34-39, especially p. 36 at Box 2; Doerks *et al.* (June 1998) "Protein annotation: detective work for function prediction." Trends in Genetics **14**(6): 248-250; Smith and Zhang (November 1997) "The challenges of genome sequence annotation or 'The devil is in the details'." Nature Biotechnology **15**:1222-1223; Brenner (April 1999) "Errors in genome annotation." Trends in Genetics **15**(4): 132-133; Bork and Bairoch (October 1996) "Go hunting in sequence databases but watch out for the traps." Trends in Genetics **12**(10): 425-427].

Due to the large quantity of experimentation necessary to generate the large number of variants and compounds recited in the claims and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Claim Rejections - 35 USC § 112, 1st paragraph, written description***

Claims 29, 31-39 and 41-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. § 112, paragraph 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of, and what Applicant is claiming.

From the specification, it is clear that Applicant has possession of an antibody to a patched-2 protein of SEQ ID NO: 2. This patched-2 protein has been demonstrated to bind a single form of each of Smoothened (SEQ ID NO: 17), 19kDa fragment of murine Sonic hedgehog protein (SEQ ID NO: 18), and Desert hedgehog (see pg 45, lines 1-24). The specification fails to describe or teach any other patched-2 protein variant that retains the characteristic of binding hedgehog or Smoothened.

The claims are not limited to an antibody to the described protein of SEQ ID NO: 2. Instead, the claims are directed to an antibody to a genus encompassing variants of the protein of SEQ ID NO: 2. The genus is highly variant because a significant number of structural differences between genus members are permitted.

The claims require that the polypeptides possess some similarity to a hedgehog polypeptide (at least 91%) and the particular conserved function of binding to hedgehog or *Smoothened* polypeptide. However, the instant specification fails to describe the entire genus of compounds that are encompassed by this genus.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a

combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features, or critical conserved regions, of the genus of patched-2 polypeptides that retain binding to hedgehog or Smoothened. There is not even identification of any particular portion of the structure of patched-2 that must be conserved. Structural features that could distinguish encoded polypeptides in the genus from others are missing from the disclosure. The specification and claims do not provide any description of what changes should be made. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides and polypeptides encompassed. Thus, no identifying characteristics or properties of the instant polypeptides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until

reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an antibody to a patched-2 protein of SEQ ID NO: 2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 112, 2nd paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 39 are indefinite because it is unclear if the phrase "and (2) which binds to hedgehog" refers to the purified antibody or to the *patched-2* polypeptide.

Claim 39 is also indefinite because it is unclear if "*Smoothened*" refers to the *Smoothened* nucleic acid or polypeptide. The use of the italicized term *Smoothened* alone indicates that the nucleic acid is referred to, but it is noted that the specification only demonstrates binding of a *patched-2* polypeptide to the *Smoothened* polypeptide. In this regard, this claim would be rendered definite if it was amended to recite, for example, "...which binds to *Smoothened* polypeptide."

The remaining claims are rejected for depending from an indefinite claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-33, 35-43, 45-49 and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoyama et al. 18 February 1998. Nat Genet. 18(2): 104-6 in view of Tso et al, U.S. Patent No. 5,932,448, published 3 August 1999, and filed 11/29/1991.

Claims 29-33, 39-43 and 49 encompass any antibody that binds to a patched-2 polypeptide of instant SEQ ID NO: 2. The remaining claims encompass any monoclonal (claims 35, 45 and 51), humanized (claims 36, 46 and 52), bispecific (claims 37, 47 and 53), or heteroconjugated (claims 8, 48 and 54) antibody that binds to a patched-2 polypeptide.

Motoyama teaches the mouse gene *Ptch2* that encodes the polypeptide patched-2. The sequence of the mouse patched-2 polypeptide is 89.3% similar to instant SEQ ID NO: 2 (which is the human patched-2 polypeptide). An alignment of the two sequences is attached to this Office Action as Sequence Alignment #1.

Motoyama does not teach an antibody to the mouse patched-2 polypeptide.

Tso teaches general methods for producing bispecific antibodies (col 1, line 62-67). Tso further teaches monoclonal antibodies for use in production of bispecific antibodies (col 7, line 19). Tso further teaches humanized antibodies for use in bispecific antibodies (col 2, lines 46-47). The instant specification defines heteroconjugated antibodies as "antibodies composed of two covalently joined antibodies (pg 26). Tso teaches chemical cross-linking of two antibodies to produce a

bispecific antibody (col 1, lines 34-35). This bispecific antibody taught by Tso meets the definition of a "heteroconjugated" antibody as defined by the specification.

It would be obvious to the person of ordinary skill in the art at the time the invention was made to make antibodies as taught by Tso to the mouse patched-2 polypeptide taught by Motoyama.

The person of ordinary skill in the art would be motivated to do so because Tso teaches that the antibodies have general uses applicable for use with any protein, such as cross-linking a horseradish peroxidase for purposes of detection (see col 11, lines 52-55).

The person of ordinary skill in the art would have expected success because Motoyama teaches the sequence of mouse patched polypeptide, and Tso teaches the methods necessary to produce antibodies to any protein sequence.

Due to the high degree of similarity between the two sequences, including numerous regions of 20 or more amino acids with 100% identity between the sequences, one of skill in the art would reasonably predict that numerous monoclonal antibodies, including bispecific, humanized, and heteroconjugated antibodies, made to mouse patched-2 polypeptide as taught by Motoyama would bind to the human patched-2 polypeptide of instant SEQ ID NO: 2.

Claims 29, 34, 39, 44, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoyama et al. 18 February 1998. Nat Genet. 18(2): 104-6, in view of Liddell et al. Antibody Technology, BIOS Scientific Publishers, 1995. Pgs 9-24 and 85-102.

Claims 29, 39 and 49 encompass any antibody that binds to a patched-2 polypeptide of instant SEQ ID NO: 2. Claims 34, 44, and 50 encompass any polyclonal antibody that binds to a patched-2 polypeptide of instant SEQ ID NO: 2.

Motoyama teaches the mouse gene *Ptch2* that encodes the polypeptide patched-2. The sequence of the mouse patched-2 polypeptide is 89.3% similar to instant SEQ ID NO: 2 (which is the human patched-2 polypeptide). An alignment of the two sequences is attached to this Office Action as Sequence Alignment #1. Motoyama further teaches

the *in situ* expression of the mouse gene *Ptch2* in the mouse "developing tooth, hair follicle and whisker" (see Figure 2).

Motoyama does not teach polyclonal antibody to the mouse patched-2 polypeptide.

Liddell teaches general methods for producing polyclonal antibodies to any protein sequence for use (see pgs 9-24) and the specific use of polyclonal antibodies in immunocytochemistry (see pg 86).

It would be obvious to the person of ordinary skill in the art at the time the invention was made to make polyclonal antibodies for immunocytochemistry as taught by Liddell to the mouse patched-2 polypeptide taught by Motoyama.

The person of ordinary skill in the art would be motivated to do so in order to determine the *in situ* expression of the mouse patched-2 polypeptide taught by Motoyama. The person of ordinary skill in the art would have expected success because Motoyama teaches the sequence of mouse patched polypeptide and *in situ* expression of the nucleic acid, and Liddell teaches the methods necessary to produce polyclonal antibodies to any protein sequence and the methods to use the antibodies in immunocytochemistry.

Due to the high degree of similarity between the two sequences, including numerous regions of 20 or more amino acids with 100% identity between the sequences, one of skill in the art would reasonably predict that numerous polyclonal antibodies made to mouse patched-2 polypeptide as taught by Motoyama would bind to the human patched-2 polypeptide of instant SEQ ID NO: 2.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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